REMARKS

Claims 23-84 were pending in the above-identified application. Claims 23-84 have been cancelled without prejudice, and claims 85-90 have been added. No new matter is believed to have been added. Support for the new claims can be found throughout the application as originally filed. Attached hereto is a marked-up version of the changes made to the claims by this Preliminary Amendment. The attachment is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

I. The Written Description Rejection

Claims 23-84 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly lacking sufficient written description. The Examiner argues that the specification fails to provide sufficient relevant identifying characteristics that identify members of the genus of antibodies that bind gp55, gp95, gp115 or gp120 antigens.

Applicant respectfully traverses to the extent the rejection may be held to apply to the new claims. Applicant notes that the *Fiers v. Sugano* recognizes that a chemical material can be claimed by means of a process and that conception can occur (and thus the written description requirement can be satisfied) when one is able to describe the chemical material by its method of preparation. *See Fiers v. Sugano*, 25 U.S.P.Q.2d 1601, 1604-1605 (Fed. Cir. 1993). For example, the "gp55" nomenclature is not an intended limitation of the claim and it is not employed in claims 85-90. Here, some of the claims do not recite an antigen by a specific structural feature, but instead, recite an antigen associated with the target hepatocellular carcinoma cells, target lymphoma cells, target colon carcinoma cells or target gastric cancer

cells. The chemical identity of the recited antigen is clearly described by the process of isolation. Methods of isolating an antibody and corresponding antigen, for example, associated with hepatocellular carcinoma cells, lymphoma cells, colon carcinoma cells or gastric cancer cells are well known in the art and are sufficiently disclosed in the specification (see, e.g., pages 15, 24 and 25). Thus, the written description requirement is satisfied by disclosing the isolation of antibody and its corresponding antigen by the method of preparation. Accordingly, the rejection is traversed and Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

II. The Enablement Rejection

Claims 23-84 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly not being enabled. The Examiner indicates that the specification has not enabled the breadth of the claimed invention in that the claims allegedly encompass an antibody with a specificity against any cell surface protein on any cancer cell recited in the claims. Respectfully, this rejection is traversed as set forth below.

In order to expedite prosecution and advance the case towards issuance, Applicant has provided new claims, some of which recite antigens associated with target hepatocellular carcinoma cells, target lymphoma cells, target colon carcinoma cells or target gastric cancer cells. Furthermore, as explained above, Applicant believes sufficient disclosure exists in the specification enabling one skilled in the art to isolate an appropriate antigen, for example, associated with target hepatocellular carcinoma cells, target lymphoma cells, target colon carcinoma cells or target gastric cancer cells (see, e.g., pages 15, 24 and 25). One skilled in the

art can make and use the antibodies and corresponding antigens made by the recited method, without undue experimentation.

The Examiner also alleges that the specification does not disclose that the monoclonal antibody described in the examples are readily available to the public, nor does the specification disclose a repeatable method for obtaining the said monoclonal antibody. As noted above, methods of isolating antibodies specific to a diseased target cell are amply described in the specification (e.g., pages 15, 24 and 25). The "gp" nomenclature is purely for convenience only and is not meant as a structural limitation. Some of the claims recite an antigen associated with hepatocellular carcinoma cells, lymphoma cells, colon carcinoma cells or gastric cancer cells and methods for isolating antibodies and antigens are well known in the art (see, e.g., pages 15, 24 and 25).

In view of the above, Applicant respectfully submits that the rejection has been traversed. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

III. The New Matter Rejection

Claims 23-84 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly containing new matter. Specifically, the Examiner states that the claims are not supported by the specification in that the dendritic cells or macrophages that are antigen pulsed or transfected with nucleic acid encoding the said antigen and that are fused with the recited tumor cells. Applicant respectfully traverses and respectfully directs the Examiner's attention to, for example, page 4, lines 8-10 of the specification. On page 4, the specification discloses dendritic cells and other types of cells fused with the recited tumor cells. "...or an antigen presenting cell presenting one or more

antigens associated with a disease (e.g., dendritic cells, macrophages, B cells, and other cells fused with diseased cell, pulsed with antigens or transfected with antigen expressing nucleic acid)." Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection in view of this traverse.

The Examiner also notes that the phrase "or their precursors" is not supported by the application as originally filed. In order to expedite prosecution and advance the case towards issuance, this phrase has been omitted from new claims 85-90. In view of the above, Applicant respectfully submits that this issue is now moot.

IV. The Indefiniteness Rejection

Claims 23-84 stand rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite.

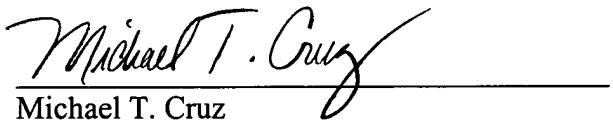
Applicant respectfully traverses to the extent the rejection may be held to apply to the new claims. In particular, the Examiner noted a grammatical informality in the phrase "a plurality of a bispecific monoclonal antibodies". Applicant has addressed the noted grammatical informality in the new claims 85-90. The Examiner also noted that the phrase "in patient mammal" should be replaced with the phrase "of patient mammal" or "of the patient mammal". Applicants have addressed these considerations in new claims 85-90.

Furthermore, the Examiner's concerns regarding the use of "gp55", "gp95", "gp115" or gp210" is also moot in view of the new claims which do not employ this nomenclature. Moreover, the recited antigenic binding site is clearly identified by its physical property and method of preparation, which is well known in the art. One skilled in the art would have no difficulty understanding the subject matter of the new claims. In view of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

CONCLUSION

Applicant believes that this Preliminary Amendment places the application in condition for allowance. The Commissioner is hereby authorized to charge any amount due or credit any overpayment to Baker & McKenzie Deposit Account No. 02-0410. Should any issues remain unresolved, the Examiner is invited to telephone the undersigned.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 23-84 were cancelled without prejudice and new claims 85-90 were added.

85. A method of preparing an immunogenic composition, comprising the steps of:

(a) providing an autologous target diseased cell;

(b) increasing concentration of primary T cell activation molecules or costimulatory T cell activation molecules in the target diseased cell;

(c) providing a bridge molecule including one or more binding sites for one or more costimulatory molecules on a surface of one or more T cells of a patient mammal;

(d) attaching the bridge molecule to the target diseased cell; and

(e) collecting a pharmaceutically effective amount of the target diseased cell with the attached bridge molecule.

86. The method according to claim 85, wherein step (b) includes the step of treating the target diseased cell.

87. An immunogenic composition, comprising:

a pharmaceutically effective amount of one or more isolated or enriched dendritic cells or macrophages which presents one or more antigens associated with target hepatocellular carcinoma cells, target lymphoma cells, target colon carcinoma cells or target gastric cancer cells, wherein the dendritic cells or the macrophages have been (i) pulsed with the one or more antigens or (ii) transfected with nucleic acid capable of expressing the one or more antigens; and

a pharmaceutically effective amount of one or more bispecific monoclonal antibodies including

one or more binding sites for one or more CD28 or 4-1BB molecules, the one or more CD28 or 4-1BB molecules being located on a surface of one or more T cells of a patient mammal, and

one or more binding sites for the one or more antigens,

wherein the bispecific monoclonal antibodies are attached to the dendritic cells or the macrophages, and

wherein the dendritic cells or the macrophages are fused with the target hepatocellular carcinoma cells, the target lymphoma cells, the target colon carcinoma cells or the target gastric cancer cells of the patient mammal.

88. A method of preparing a pharmaceutical composition, comprising the steps of:

(a) providing a plurality of dendritic cells or a plurality of macrophages that are at least one of:

(i) pulsed with one or more antigens associated with target hepatocellular carcinoma cells, target lymphoma cells, target colon carcinoma cells or target gastric cancer cells, and

(ii) transfected with nucleic acid capable of expressing the one or more antigens;

(b) associating the one or more antigens with the dendritic cells or the macrophages;

(c) providing bispecific monoclonal antibodies including (i) one or more binding sites for one or more CD28 or 4-1BB molecules, the CD28 or 4-1BB molecules being located on a

surface of one or more T cells of a patient mammal, and (ii) one or more binding sites for the one or more antigens;

(d) attaching the bispecific monoclonal antibodies to the dendritic cells or the macrophages; and

(e) collecting a pharmaceutically effective amount of the dendritic cells or the macrophages with the bispecific monoclonal antibodies attached thereto, wherein the dendritic cells or the macrophages are fused with the target hepatocellular carcinoma cells, the target lymphoma cells, the target colon carcinoma cells or the target gastric cancer cells of the patient mammal.

89. The method according to claim 88, wherein steps (c) and (d) are both performed either before or after step (b).

90. The method according to claim 88, further comprising the step of:

(f) attaching the bispecific monoclonal antibodies to the one or more CD28 or 4-1BB molecules.